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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/681,262 | 10/09/2003 | Victor V. Nekrasov | NEKRASOV2 | 5994 |
| 1444 7590 11/23/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | EXAMINER GAKH, YELENA G | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/681,262 | NEKRASOV ET AL. |
| | Examiner | Art Unit |
| | Yelena G. Gakh, Ph.D. | 1797 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 October 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment to the specification and claims filed on 10/09/07 is acknowledged. Claims 1-6 are pending in the application.

Response to Amendment

2. In response to the amendment the examiner changes objections to the specification, rejection of the claims under 35 U.S.C. 112, second paragraph, withdraws rejection of the claims under 35 U.S.C. 112, first paragraph, and establishes rejections over the prior art for the amended claims reciting the clarified subject matter.

Information Disclosure Statement

3. The examiner respectfully requests the Applicants to provide the references most pertinent to the instant application, specifically those of Nekrasov (Thesis presented at the Conference in Pushchino, 2000) and corresponding pages from Beyermann, 1982, which disclose simultaneous application of three spectroscopic methods, if any, along with the IDS form, for consideration by the examiner.

Specification

4. The specification is objected to as being unclear regarding Figures 1 and 2. On page 6, paragraph [0011], the specification refers to the luminescent spectra of trace impurities described in the prior art and points to Figures 1 and 2. Therefore, it is not clear, if Figures 1 and 2 describe the prior art, in which case they should be titled “Prior Art”, or they describe spectra of the instant invention. If the spectra are obtained by the inventors, this should be clearly indicated in the specification.

5. The specification is objected to because it does not “contain a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same”.

To the examiner’s understanding, the specification is a translation from Russian, which explains a plurality of technical errors and misinterpretation of the terms. Since the specification

repeats mostly the subject matter recited in the claims, the objection to the specific paragraphs in the specification is similar to the rejections of the claims under the second paragraph of 35 U.S.C. 112 provided below.

The original specification does not disclose any expression resembling the one that the examiner objected to in the previous Office action, namely: “a specially made-up mixture or multi-component solutions *of a strictly identical constant compound*” (e.g. [0036]). The original specification discloses the following: “a specially composed mixture or multi-component solution with well defined spectral characteristics, whose absorption or reflection spectra and luminescence spectrum overlap with the spectra of the known mixture within the selected analytical spectral ranges λ_i and λ_j , i.e. which have a non-zero intensities in the indicated ranges”.

The conventional term for “a wide-band source” is “a broadband source”.

The examiner concludes that the plurality of technical errors in the specification and claims is the result of a poor translation of the original document and therefore respectfully requests the Applicants to reconsider the present translation and provide corresponding corrections.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “a method for assaying multi-component mixtures”. Since the term “assaying” is conventionally used in the meaning of “analysis”, and there is no true analysis performed in the instant method, the examiner suggests changing the preamble of claims 1 and 2 to e.g. “a method for authenticating the composition of multi-component mixtures and/or detecting the presence of impurities in multi-component mixtures, comprising”.

The conventional term for “a wide-band source” is “a broadband source”.

To the examiner's understanding, what is meant in claim 1 regarding the term "monochromatic light" obviously refers to monochromatic light with wavelengths $\lambda_1, \lambda_2, \dots \lambda_m$, rather than "monochromatic light with a spectral width of Δ_l ". The examiner interprets the preamble and the first step of Claim 1 as the following: "A method for controlling the composition of multi-component mixtures and/or detection the presence of impurities in multi-component mixtures, comprising: a, decomposing light from a broadband source into spectral components, and/or selecting a narrow spectral band of a spectral width Δ_i from the light from the broadband source within the predetermined spectral range comprising monochromatic wavelengths λ_i , while providing an option to change the spectral position of the spectral band with a predetermined step of $\Delta\lambda_i \geq \Delta_l$ ". "Wavelength" should be written as one word.

The examiner suggests deleting [having a specific geometric shape] in step b. Also, step b) should start with the small letter "f", since the claim should comprise only one sentence.

In step c) the examiner suggests rewriting the step as the following: "c, irradiating the sample of a known mixture K and the sample of an unknown mixture U in turns with the focused probing beam at the *selected wavelengths* $\lambda_1, \lambda_2, \dots \lambda_m$ from the *predetermined spectral range* λ_i ". The examiner suggests changing the expression "extracted wave-lengths" to "selected wavelengths" and "selected spectral range" to "predetermined spectral range" throughout all claims and the specification (using "replace" option in Word).

There are several questions regarding the following steps. From step e) it is not apparent, as to how the probing beam intensity I_0 is being measured, when it is transferred into the passed and/or reflected light? Is there a special calibration channel for measuring this intensity? If this is so, it should be clearly recited in the claim; or at least the claim should refer to the reference beam I_0 . The part of the claim reciting luminescence light is unclear. If the wavelengths of the luminescence light radiated by the sample are different from the wavelengths of the incident light, this should be clearly indicated in the claim, which is not at present. It is not clear, as to how the luminescent light is generated - if the luminescent light is radiated by the sample, this also needs to be indicated in the claim.

It is totally unclear, as to why and how the luminescent light is decomposed; it is unclear, as to why the decomposed luminescent light has the same wavelengths as the incident light, as

can be seen from the first members of the set of wavelengths: $\lambda_1, \lambda_2, \dots$; at the same time it has the wavelengths different from the wavelengths of the incident light: λ_m vs. λ_n . Clarification regarding the set of wavelengths of the incident light and luminescent light radiated by the sample should be provided.

The whole step e) has obvious grammar problems, which need to be corrected as well.

Step f) should recite “determining”, rather than “Defining”. The term “gathered” should be replaced with “collected”. The examiner respectfully requests the Applicants to establish consistency of the terminology used throughout the claims and the specification.

The expression “the light passing through a sample” should be replaced with the “light passed through the sample”.

The definite article “the” should be used for “the sample” in all claims, since it is the same sample recited in all claims.

To the examiner’s understanding, luminescent light is defined by two wavelengths, with one being the wavelength of the incident light, and the other one - the wavelength of the luminescent light radiated by the sample, which is not clear from the claim. Clarification is required.

In step f) the examiner suggests using the following description of the terms from the equation: “ ... - intensities of passed or reflected light for the sample of the known (K) mixture and unknown (U) mixture measured at the selected wavelengths $\lambda_1, \lambda_2, \dots \lambda_m$ of the incident light from the predetermined range λ_i ;

... - intensities of the luminescent light radiated by the sample of the known (K) mixture and unknown (U) mixture measured at the selected wavelengths $\lambda'_1, \lambda'_2, \dots \lambda'_m$ upon irradiating the sample with the monochromatic light at the selected wavelengths $\lambda_1, \lambda_2, \dots \lambda_m$ from the predetermined spectra range λ_i .

... - calibrating intensities of the incident light, which irradiates the sample of the known (K) mixture and unknown (U) mixture at selected wavelengths $\lambda_1, \lambda_2, \dots \lambda_m$.

Definitions for the terms T and L should be provided in step f), rather than step g).

Step g) is suggested to recite the following: “comparing corresponding relative intensities of the light passed through the sample or reflected by the sample at each of the selected wavelengths

λ_m and of the luminescent light at each of the selected wavelengths λ'_m measured for the selected wavelengths λ_m of the incident light for the sample of the known mixture and the sample of the unknown mixture, and determine compliance of the unknown mixture to the known mixture according to the equation:

..., where

T.... - intensities of passed or reflected light for the samples of the known (K) mixture and unknown (U) mixture, normalized for the intensity of the incident light at the corresponding wavelengths;

L.... - intensities of luminescent light radiated by the samples of the known (K) and unknown (U) mixtures at the selected wavelengths $\lambda'_1, \lambda'_2, \dots \lambda'_m$ within the predetermined range λ'_m upon irradiating the samples with the incident light at the selected wavelengths $\lambda_1, \lambda_2, \dots \lambda_m$ within the predetermined range λ_m , wherein the intensities are normalized for the intensity of the incident light at the corresponding wavelengths;

m, n - the number of selected wavelengths from the predetermined spectral ranges λ_i and λ_j , respectively;

δ - acceptable deviation for the values of quantities of the unknown mixture from the values of the corresponding quantities for the known mixture;

In step h) replace [Defining] with -- defining -- and replace [at the same time, if] with -- whereas, if, the foreign impurities in the sample under analysis are absent, while if there are ranges with ..., the conclusion can be drawn that the undesirable impurities are present".

All the remaining claims should be amended correspondingly.

The specification should be amended correspondingly.

The translation of claim 6 does not correspond to the original. Original claim 6 can be translated as the following: "The method of claim 1, wherein the method comprises detection of multi-component impurities in aqueous systems".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 5,121,337) in view of Voropai et al. (J. Appl. Spectr., 2000).

Brown teaches the following:

"The invention relates, in its broadest aspect, to a method of correcting spectral data of a number of samples for the effects of data arising from the measurement process itself (rather than from the sample components), but it finds particular application to estimating unknown property and/or composition data of a sample where the estimation includes steps to effect the aforesaid correction for the measurement process spectral data. The spectral data for n calibration samples is quantified at f discrete frequencies to produce a matrix X (of dimension f by n) of calibration data. The first step in the method involves producing a correction matrix U_m of dimension f by m comprising m digitised correction spectra at the discrete frequencies f, the correction spectra simulating data arising from the measurement process itself. The other step involves orthogonalizing X with respect to U_m to produce a corrected spectra matrix X_c whose spectra are orthogonal to all the spectra in X_m. Due to this orthogonality, the spectra in matrix X_c are statistically independent of spectra arising from the measurement process itself" (col. 3, lines 5-20).

"When applying the technique for correcting for the effects of measurement process spectral data in the development of a method of estimating unknown property and/or composition data of a sample under consideration, the following steps are performed. Firstly, respective spectra of n calibration samples are collected, the spectra being quantified at f discrete frequencies (or wavelengths) and forming a matrix X of dimension f by n. Then, in the manner described above, a correction matrix U_m of dimension f by m is produced. This matrix comprises m digitised correction spectra at the discrete frequencies f, the correction spectra simulating data arising from the measurement process itself. The next step is to orthogonalize X with respect to U_m to produce a corrected spectra matrix X_c whose spectra are each orthogonal to all the spectra in U_m. The method further requires that c property and/or composition data are collected for each

of the n calibration samples to form a matrix Y of dimension n by c ($c \geq 1$). Then, a predictive model is determined correlating the elements of matrix Y to matrix X_c . Different predictive models can be used, as will be explained below. The property and/or composition estimating method further requires measuring the spectrum of the sample under consideration at the f discrete frequencies to form a matrix of dimension f by 1. *The unknown property and/or composition data of the samples is then estimated from its measured spectrum using the predictive model. Generally, each property and/or component is treated separately for building models and produces a separate f by 1 prediction vector.* The prediction is just the dot product of the unknown spectrum and the prediction vector. By combining all the prediction vectors into a matrix P of dimension f by c, the prediction involves multiplying the spectrum matrix (a vector of dimension f can be considered as a 1 by f matrix) by the prediction matrix to produce a 1 by c vector of predictions for the c properties and components” (col. 7, lines 49-68, col. 8, lines 1-19).

While Brown's matrices do not appear to comprise elements, each of which represent a ratio of the intensities of the absorbed light of the unknown sample relative to the known and/or calibration samples at each wavelength (a discrete frequency f), it would have been obvious for a person of ordinary skill in the art to deduce such matrices, because they represent a finer normalization of the spectra in respect to the hardware errors (when using calibration samples), and/or determining the presence of the signals from other components in the unknown samples relative to known samples (when using the spectra of the known samples), than Brown's matrices based on performing Principal Component Analysis (PCA), (col. 13, Introduction).

Brown does not disclose performing absorption and luminescence spectroscopic analysis with the same samples, although he indicates:

“It is also remarked that the spectra can be absorption spectra and the preferred embodiments described below all involve measuring absorption spectra. However, this is to be considered as exemplary and not limiting on the scope of the invention as defined by the appended claims, since the method disclosed herein can be applied to other types of spectra such as reflection spectra and scattering spectra (such as Raman scattering)” (col. 3, lines 47-55).

Brown also does not specifically teach analysis of multi-component mixtures of impurities in aqueous systems.

Voropai teaches “determination of the luminescent impurity concentration in solution in the presence of intense background luminescence” in relation to detecting polycyclic aromatic hydrocarbon (PAH) impurities in aqueous systems (see Introduction), indicating: “a large number of publications are devoted to the spectrofluorometric methods of analyzing multicomponent mixtures. ... In the 1970s-1980s, the so-called methods of total least squares and nonnegative least sum of errors were used for analyzing multicomponent mixtures” (page 1031).

"It is known that the excitation and luminescence spectra of PAHs in solutions at room temperature have a rather distinct structure (see, for example, Fig. 1a). Of these characteristics excitation-emission spectra are considered as a "fingerprints" of a give material in a given solvent, the problem on determination of this material reduces to the recognition of these "prints" in the common EEM [excitation-emission matrix, Ex.]".

"The luminescence intensity in an excitation-emission spectrum is given in the form of the function $I(\lambda_{\text{exc}}, \lambda_{\text{lum}})$. The registered EEM of size $m \times n$ corresponding to this function will be designated as I . The EEM elements $I(i,j)$ correspond to the values of the luminescence intensity of the investigated sample containing an anthracene impurity" (page 1032). Formula for EEM comprises signal intensities from luminescence, as well as Raman scattering (Claim 3).

It would have been obvious for any person of ordinary skill in the art to further modify Brown's method comprising developing matrices, each element of which is a ratio of intensities of the absorption and/or reflection spectra for the unknown multicomponent mixture relative to the standard and/or the known multicomponent mixture taken for each selected wavelength (frequency f) with adding excitation-emission matrix for the multicomponent mixtures, which may have luminescent impurities, as disclosed by Voropai, because such impurities have specific "fingerprints", which would assist in completing the results of Brown's analysis with specific signatures of luminescent impurities.

It would have been obvious for any person of ordinary skill in the art to replace measuring the spectra for known multicomponent mixtures with their electronic luminescent signatures, as recited in Claim 2, and/or Raman spectra, as recited in claim 4, because, as indicated by Voropai, such spectra are fingerprints for specific multi-component mixtures, and therefore can be used as references for identifying the unknown multicomponent mixtures.

Response to Arguments

Applicant's arguments filed 10/09/07 have been fully considered but they are not persuasive. Regarding the language of the claims and the specification, while a part of the specification and claims have been amended, the corrections were not made through all claims

and the specification, and therefore the language became inconsistent. The examiner provided some examples of possible amendment in the present Office action.

Since the subject matter of the claims as originally filed was difficult to understand, and it required the amendment of the claims and multiple interviews with the inventors to clarify the recitation of the claims, the examiner was not able to apply any prior art in the previous Office action, which she does in the present Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/19/07



YELENA GAKH
PRIMARY EXAMINER